

Message

From: Jones, Russell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4795FDC630C34BE4AED0C6416A20D606-RUSSELL JONES]
Sent: 4/1/2020 4:24:27 PM
To: Simons, Eddie (AGR) [ESimons@agr.wa.gov]; Burnett, Gina [Burnett.Gina@epa.gov]
CC: Schulze, Chad [Schulze.Chad@epa.gov]; sfoss@agr.wa.gov
Subject: RE: 3064 Fertilizer Application Issues

Eddie:

My only caveat is that the Draft Guidance is not official and has been updated in response to the comments received (update is still under internal review).

Russ J

Russell S. Jones, Ph.D., Senior Scientist
Chair, Biochemical Classification Committee
Risk Assessment Branch
Biopesticides & Pollution Prevention Division
Office of Pesticide Programs
US Environmental Protection Agency

P: 703-308-5071; F: 703-308-7026
jones.russell@epa.gov

Office Location:
One Potomac Yard
2777 South Crystal Drive Arlington, VA 22202

Mailing Address:
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001
<http://www.epa.gov/pesticides>



From: Simons, Eddie (AGR) <ESimons@agr.wa.gov>
Sent: Wednesday, April 01, 2020 12:14 PM
To: Burnett, Gina <Burnett.Gina@epa.gov>
Cc: Jones, Russell <Jones.Russell@epa.gov>; Schulze, Chad <Schulze.Chad@epa.gov>; sfoss@agr.wa.gov
Subject: FW: 3064 Fertilizer Application Issues

Hello Gina,

Do you agree with my assessment below that this product is making pesticide (plant regulator) claims and should be reviewed under M009 for registration eligibility? I have attached the proposed label and a snip of the website (<https://kimitecagro.com/en/product/bombardier-sugar/#description>) your convenience. I have also referenced Tables 3 & 4 from the EPA Draft Guidance in my response to the registrant.

Thank you,

Eddie Simons
Registration Specialist

Washington State Department of Agriculture
Pesticide Management Division



From: Simons, Eddie (AGR)
Sent: Wednesday, April 01, 2020 9:04 AM
To: 'David Martinez Sáez' <dmartinez@kimitec.es>
Subject: RE: 3064 Fertilizer Application Issues

Hello David,

I am sorry about the confusion. I still have not received anything to indicate that the product is functioning as a fertilizer and not as a plant regulator. Have you contacted EPA for a determination of the registration eligibility of this product, Bombardier Sugar 4-0-0?

- The product label still directs the user to apply less than 1 lb of total nitrogen per acre per application. That is not a fertilizer application.
- The label is still directing the user to foliar apply fulvic acid, a plant regulator application according to EPA. [Table 4 – Complex Polymeric Polyhydroxy Acids (including Humic acid, fulvic acid, tannins; & organic acids from Leonardite) *Foliar applications only...*]
- The product label is still indicating that the product “...increases the synthesis of SACAROSE.” [Table 3 – Enhances/promotes/stimulates fruit growth & development – Enhances/promotes crop/fruit/produce color/development/quality/shape]
- The product label is still claiming to have “...a direct effect in ripening and increasing Degrees Brix (°Bx).” [Table 3 – Enhances/promotes/stimulates fruit growth & development – Accelerates/controls/delays abscission/development/ripening/senescence – Enhances/promotes crop/fruit/produce color/development/quality/shape – Enhances/promotes fruit growth & development]
- The product label is still claiming to improve the size and quality of fruit. [Table 3 – Enhances/promotes crop/fruit/produce color/development/quality/shape – Enhances/promotes fruit growth & development]
- In addition, the website (<https://kimitecagro.com/en/product/bombardier-sugar/#description>) is making many claims, such as:
 - “...stimulate and increase the levels of monosaccharides, oligosaccharides and polysaccharides in the fruit.” [Table 3 – Enhances/promotes/stimulates fruit growth & development – Enhances/promotes crop/fruit/produce color/development/quality/shape]
 - “...achieving a direct effect on maturation, coloring and ultimately favoring an increase in Brix degrees.” [Table 3 – Enhances/promotes/stimulates fruit growth & development – Accelerates/controls/delays abscission/development/ripening/senescence – Enhances/promotes crop/fruit/produce color/development/quality/shape – Enhances/promotes fruit growth & development]
 - “To obtain optimum results we have incorporated in the formulation, in addition to the compounds previously mentioned (amino acids, fulvic acids, organic matter and oligosaccharides), elements such as Fe, K, Betaines, proteins, enzymes, auxins and vitamins. This second group enables BOMBARDIER SUGAR to reach optimum results in ripening levels and green organ development, as well as an increase in fruit size and quality.” [Claims to contain unlabeled nutrients (Fe and K) and unregistered pesticides (auxins). Plus, Table 3 – Enhances/promotes/stimulates fruit growth & development – Accelerates/controls/delays abscission/development/ripening/senescence – Enhances/promotes crop/fruit/produce color/development/quality/shape – Enhances/promotes fruit growth & development]

Therefore, I still need data to support the use of this product as a fertilizer. All claims are for non-fertilizer purposes. In addition, it appears to be an unregistered pesticide. I still recommend that you contact EPA for a M009 review. Registration as a fertilizer does not exclude a product from the definition of a pesticide.

As you mentioned, similar products are registered with WSDA. Since they were registered, WSDA Registration Services has become more educated in the nuances of plant regulator compounds and claims. WSDA is currently working on moving such products to the pesticide registration route, as the laws require.

Regards,

Eddie Simons
WSDA

From: David Martinez Sáez [<mailto:dmartinez@kimitec.es>]
Sent: Tuesday, March 31, 2020 12:13 AM
To: Simons, Eddie (AGR) <ESimons@agr.wa.gov>
Subject: RE: 3064 Fertilizer Application Issues

Dear Simon,

We submitted some time ago attached label, in response to your email pointing some issues that need to be solved for the registration of the product Bombardier Sugar, but we haven't received any response. Could you please confirm if any additional change would be needed?

Best regards,
David

De: David Martinez Sáez
Enviado el: jueves, 5 de diciembre de 2019 12:02
Para: Simons, Eddie (AGR) <ESimons@agr.wa.gov>
CC: Schulze, Chad <Schulze.Chad@epa.gov>; Russ Jones (jones.russell@epa.gov) <jones.russell@epa.gov>
Asunto: RE: 3064 Fertilizer Application Issues

Good morning Simon,

I have been talking to our distributor in USA; until now they were the registration holders of this product in Washington and they used the same label I previously submitted to register the product, that's why I didn't want to make any changes.

Regarding the source of nitrogen, I have updated the derived from statement in the same way we express it in other States like California: sugar beet protein hydrolysate. We have also removed the claims you mention in your email.

We have seen that there are similar products already registered, please let us know if any additional changes would be needed.

Regards,
David

De: Simons, Eddie (AGR) <ESimons@agr.wa.gov>
Enviado el: jueves, 28 de noviembre de 2019 1:34
Para: David Martinez Sáez <dmartinez@kimitec.es>

CC: Schulze, Chad <Schulze.Chad@epa.gov>; Russ Jones (jones.russell@epa.gov) <jones.russell@epa.gov>

Asunto: 3064 Fertilizer Application Issues

Hello David,

I did a quick review of the label you submitted for registration as a fertilizer and I have a few issues that need to be resolved.

1. The product does not appear to be functioning as a fertilizer.
 - a. At maximum labeled application rates, the crop would receive less than 1 pound of Total Nitrogen (N) per acre per application. This is not enough nutrition to make any difference to the crop. The product must have a non-fertilizer function.
 - b. The product guarantees Total Nitrogen yet there is not a recognized source of nitrogen in the Derived from statement.
2. Some of the claims may be plant regulator claims. See the EPA Draft Guidance for Plant Regulator Label Claims, Including Plant Biostimulants. <https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0258-0002>
 - a. Improves ripening
 - b. Increases fruit size and quality

I recommend that you remove the nitrogen guarantee and contact EPA to get a determination on the pesticide registration eligibility of this product. More information on getting a determination from EPA can be found at: <https://www.epa.gov/pria-fees/m009-pria-fee-category>

Please address these concerns by Monday, December 9, 2019. If you are unable to comply with these requests, you may withdraw the application to register these products at this time.

Regards,

Eddie Simons

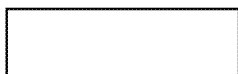
Registration Specialist

Washington State Department of Agriculture

Pesticide Management Division

Phone: 360.902.2031

email: esimons@agr.wa.gov



David Martinez Sáez

Regulatory Affairs Manager | Regulatory

dmartinez@kimatec.es

+34 625198846

Skype: dmartinez@kimatec.es

www.kimatecgroup.com

Este mensaje y sus adjuntos contienen información confidencial y reservada dirigida exclusivamente a su destinatario. Si ha recibido este mensaje por error, se ruega lo notifique inmediatamente por esta misma vía y borre el mensaje de su sistema. Nótese que el correo electrónico vía Internet no permite asegurar ni la confidencialidad de los mensajes que se transmiten ni la correcta recepción de los mismos. En cumplimiento de la normativa vigente en materia de Protección de Datos de Carácter Personal, le informamos que los datos derivados de su correspondencia serán tratados por **AGROINDUSTRIAL KIMATEC, S.L. , KIMATEC BIOGROUP, S.L. , AGROCODE BIOSCENCE, S.L. , CANNABIS BIOTECHNOLOGICAL DEVELOPMENTS, S.L.** con la finalidad de gestionar las comunicaciones que pudiera mantener con el personal de la entidad. Los datos personales proporcionados se conservarán, mientras no se solicite su supresión por el interesado o se mantenga la relación con esta empresa. La legitimación para el tratamiento de datos se basa en la relación que mantiene con esta empresa. Para darse de baja o ejercer sus derechos de acceso, rectificación, supresión, limitación de tratamiento, oposición, portabilidad, derecho a no ser objeto de decisiones individuales automatizadas, así como la revocación del consentimiento prestado, puede realizarlo dirigiéndose por escrito a la dirección **Paraje Cerro de Los Lobos S/N - 04738 VÍCAR (ALMERIA)**. O por mail a lpd@kimatec.es

This message and its attachments contain confidential and restricted information directed exclusively to its recipient. If you have received this message by mistake, please notify us immediately to track and delete the message from your system. Please note that the e-mail via the Internet does not guarantee the confidentiality of the messages that are sent or the correct reception of them. In compliance with the regulations in force regarding the protection of personal data, we inform you that the data derived from your correspondence will be processed by **AGROINDUSTRIAL KIMATEC, S.L. KIMATEC BIOGROUP, S.L. AGROCODE BIOSCENCE, S.L. , CANNABIS BIOTECHNOLOGICAL DEVELOPMENTS, S.L.** in order to manage the communications you may maintain with the staff of the entity. The personal data provided will be retained, until the deletion is requested by the person concerned or if the relationship with this company is maintained. Legitimation for data processing is based on the relationship maintained with this company. To unsubscribe or exercise your rights of access, rectification, suppression, limitation of treatment, opposition, portability, the right not to be the subject of automated individual decisions, as well as the revocation of the consent given, you can contact us in writing at the address **Paraje Cerro de Los Lobos S/N - 04738 VÍCAR (ALMERIA)**. Or by mail lpd@kimatec.es